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ORIGINAL INVESTIGATION
ÖZGÜN ARAŞTIRMA

The Evaluation of the Parameters Affecting Flap Thickness in LASIK Surgery

LASIK Cerrahisinde Flep Kalınlığını Etkileyen Parametrelerin Değerlendirilmesi

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ABSTRACT
ÖZET

Objective: To evaluate the factors affecting flap thickness (FT) in LASIK surgery using the MK-2000 microkeratome.

Materials and Methods: One hundred and fifty-nine eyes of 82 cases with myopia and/or myopic astigmatism who underwent LASIK surgery were included. The MK-2000 microkeratome was used in all cases. The patients were divided into two groups according to microkeratome heads (Group 1: 130 μm, Group 2: 160 μm). The actual FT was calculated by subtracting the pachymetric thickness of the central corneas before and after lifting the flap. The impact of age, preoperative central corneal thickness (CCT), and refractive and keratometric values on FT was determined. In addition, the possible effects of the first and second usage of the same microkeratome were also evaluated in cases with bilateral LASIK surgery.

Results: The mean FT was found to be lower in the study group (t=21.35 and t=18.78, P<0.001) than expected. There was a significant positive correlation between FT and preoperative CCT. In bilateral LASIK cases, FT was not significantly different between the first and second eyes in Group 1. However, the FT values of the first eye were found to be thicker than those of the second eye in Group 2.

Conclusion: Although the obtained FT values were thinner than the expected theoretical FT, we did not encounter any microkeratome-related flap complications. Therefore, the MK-2000 microkeratome may be used as a reliable and safe method for LASIK surgery.

Key words: Cornea, LASIK, microkeratome

Amaç: MK-2000 mikrokeratom kullanılarak yapılan LASIK cerrahisinde flep kalınlığını etkileyen parametreleri değerlendirmek.

Gereç ve Yöntemler: LASIK cerrahisi uygulanmış, miyopik ve/veya miyopik astigmatizması olan 82 olgunun 159 gözü çalışmaya dahil edildi. Tüm olgularda MK-2000 mikrokeratom kullanıldı. Olgular kullanılan mikrokeratom başlığına göre 2 gruba ayrıldı (1. Grup: 130 μm, 2. Grup: 160 μm). Gerçek flep kalınlığı, flep kaldırılmadan önceki ve sonraki pakimetrik santral kormeal kalınlıkların çıkarılması ile hesaplandı. Yaş, ameliyat öncesi santral korneal kalınlık (SKK), refraktif ve keratometrik değerlerin flep kalınlığına etkisi değerlendirildi. Ayrıca bilateral LASIK cerrahisi uygulanan olgularda aynı mikrokeratomun birinci ve ikinci kez uygulanmasının da flep kalınlığına olası etkileri araştırıldı.

Bulgular: Ortalama flep kalınlığı çalışma grubunda beklenenden (1. Grup: 130 μm, 2. Grup: 160 μm) düşük bulundu (t-değerleri= 21,35 ve 18,78; P<0,01). Flep kalınlığı ile operasyon öncesi SKK arasında istatistiksel olarak anlamlı pozitif bir ilişki bulundu. Bilateral LASIK olgularında, 1. Grupta flep kalınlığı birinci ve ikinci gözler arasında farklı değildi. Öte yandan, 2. Grupta ilk gözlerde ikinci gözlerdekinden anlamlı şekilde daha kalın olduğu bulundu.

Sonuç: Her ne kadar ölçülen gerçek flep kalınlığı teorik olarak beklenen flep kalınlığından ince olsa da, çalışmaya alınan olgularda mikrokeratom ile ilişkili flep komplikasyonuna rastlanmadı. Bu nedenle, MK-2000 mikrokeratomun LASIK cerrahisi için önceden kestirilebilir ve güvenilir bir yöntem olarak kullanılabilir.

Anahtar kelimeler: Kornea, LASIK, mikrokeratom

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Introduction

Laser in situ keratomileusis (LASIK) is still the most popular procedure in refractive surgery (1-4). The general approval of LASIK is mainly based on its postoperative refractive stability and the expected quick recovery (5). LASIK surgery is basically accomplished by a microkeratome, which cuts a circular slice through the cornea (flap), leaving an uncut part (hinge) as an attachment point between the flap and the corneal bed (6). Today, various microkeratomes are in clinical use (7). Various studies performed with different microkeratomes have shown that the mean flap thickness (FT) values could be significantly different to the intended FT values (8). Obtaining a thinner flap than expected appears to be the most common problem with the majority of microkeratomes (7-9).

Corneal ectasia, which is the worst postoperative LASIK complication, is believed to be caused by the weakening of the biomechanical structure of the cornea (10-12). There is some evidence that iatrogenic keratectasia secondary to LASIK surgery might result from a large variation in FT values (13). Additionally, thicker flaps can reduce residual stromal bed, compromising the structural integrity of the cornea and the degree of refractive correction, while thin flaps have the tendency to develop striae that are difficult to manipulate (6). The incidence of microkeratome-related flap complications has been reported to range from 0.3% to 1.9% (14). Differences between the first and second eyes operated with the same blade have also been reported (15).

In this study, clinical and demographic parameters were evaluated that may have an impact on the actual FT, including the patient's age, preoperative central corneal thickness (CCT), refraction, keratometry readings, and first or second usage of the blade.

Materials and Methods

This study was approved by the Institutional Review Board of the University. The research protocol adhered to the tenets of the Declaration of Helsinki for clinical research. Written informed consent was obtained from all the participants after an explanation of the purpose and possible consequences of the procedures.

One hundred and fifty-nine eyes of 82 patients with myopia or myopic astigmatism were operated by LASIK surgery using the Nidek EC 5000 CX Excimer Laser (NIDEK Co Ltd, Gamagori, Japan) and the Nidek MK-2000 model microkeratome (NIDEK Co Ltd, Gamagori, Japan). All eyes were operated at the same clinic by the same surgeon (K.E.) using two different microkeratome heads (130 µm and 160 µm). All patients underwent a complete ophthalmological examination including uncorrected and best corrected visual acuity (VA), intraocular pressure measurement by the Goldmann applanation tonometer, evaluation of anterior segment and anterior vitreous by slit-lamp biomicroscopy, and fundus examination from dilated pupilla by slit-lamp biomicroscopy with 90 D lens, the Schirmer test, CCT by ultrasonic pachymeter (Nidek model 1000, NIDEK Co Ltd, Gamagori, Japan), and corneal topography (Nidek OPD scan model ARK-10000, NIDEK Co Ltd, Gamagori, Japan). The preoperative CCT and thickness of the stromal bed after cutting and lifting the flap were measured five times at the centre of the cornea and the averages were recorded.

The exclusion criteria were: being younger than 18 years of age, and having a history of active eye inflammation, glaucoma, ocular trauma or surgery, and any ocular surface disease including various types of corneal dystrophies, keratoconus, and dry eye disease.

Corneal anaesthesia was achieved by topical 0.5% Proparacaine Hydrochloride Ophthalmic Solution (Alcaine, Alcon) before surgery. The right eye was always treated first. The same blade was used for both eyes. The same suction ring (9.5 mm diameter) was used for all patients. Microkeratome heads (130 µm and 160 µm) were chosen according to the preoperative refraction and CCT of the patient. After creation of a nasal-hinged flap, stromal bed thickness was immediately measured and FT was calculated by subtracting the thickness of the remaining central stromal bed from preoperative CCT. Finally, the stromal bed was ablated using the Nidek EC 5000 CX Excimer Laser (NIDEK Co Ltd, Gamagori, Japan).

The patients were divided into two groups according to the microkeratome head used: 130 µm (Group 1) and 160 µm (Group 2). The effects of age, preoperative CCT, corneal keratometry, and refraction values on the actual FT were determined. Moreover, the effects of first and second usage of microkeratome blades on the flap in bilateral LASIK operations, which were carried out on the same day, were evaluated in the study.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences version 12.0 for Windows[â] system (SPSS[â] Inc, Chicago, Illinois, USA). Normality tests were performed by the Shapiro-Wilk test. Preoperative clinical variables of group 1 and group 2 patients at baseline and the difference in FT values between the right and left eyes for both groups were compared using the *t*-test. One sample *t*-tests were used to compare intended and obtained FT values. Quantitative variables were expressed as mean±SD, and qualitative variables were expressed as frequencies and percentages. Pearson correlation was used for association assessment. All statistical tests were two-sided, and a *p*-value of less than 0.05 was considered to be significant.

Results

There were 42 male (50.6%) and 40 female (49.4%) patients in the study. No statistically significant correlation was found between age and FT in the two groups (p>0.05).

There were 34 patients (64 eyes) in group 1 and 48 patients (94 eyes) in group 2. The mean spherical equivalent, CCT, and keratometric values for each group are presented in Table 1. There were statistically significant differences between the two groups in CCT (t=6.300, p<0.001) and keratometric values (t=4.307, p<0.001). However, the difference in spherical equivalent values between the two groups was not significant (t=0.580, p=0.563). Statistically significant differences were found when the intended and achieved FT values were compared (Table 2).

A significant positive correlation was found between the obtained FT and preoperative CCT (r=0.625, p<0.001). Significant negative correlations were found between FT and the preoperative keratometric power (r=0.306, p<0.001) and between FT and the preoperative cylindrical refraction values (r= 0.217, p<0.01) (Figure 1). There were no correlations between FT and spherical equivalent values.

In bilateral cases, the right eye was always operated first and then the same blade was used for the left eye. Thirty patients in group

Table 1. Preoperative clinical data in the study groups (group 1: 130 µm microkeratome head, group 2: 160 µm microkeratome head)

Parameters	Group 1 (n=34)	Group 2 (n=48)	t	p
Spherical Equivalent (diopter)	-4.2±2.0	-3.9±1.7	0.580	=0.563
Keratomeric Value (diopter) keratometric	44.2±1.4	43.1±1.4	4.307	<0.001
Central Corneal Thickness (µm)	523.9±34.4	556.2±29.4	6.332	<0.001

All data are presented as mean±SD

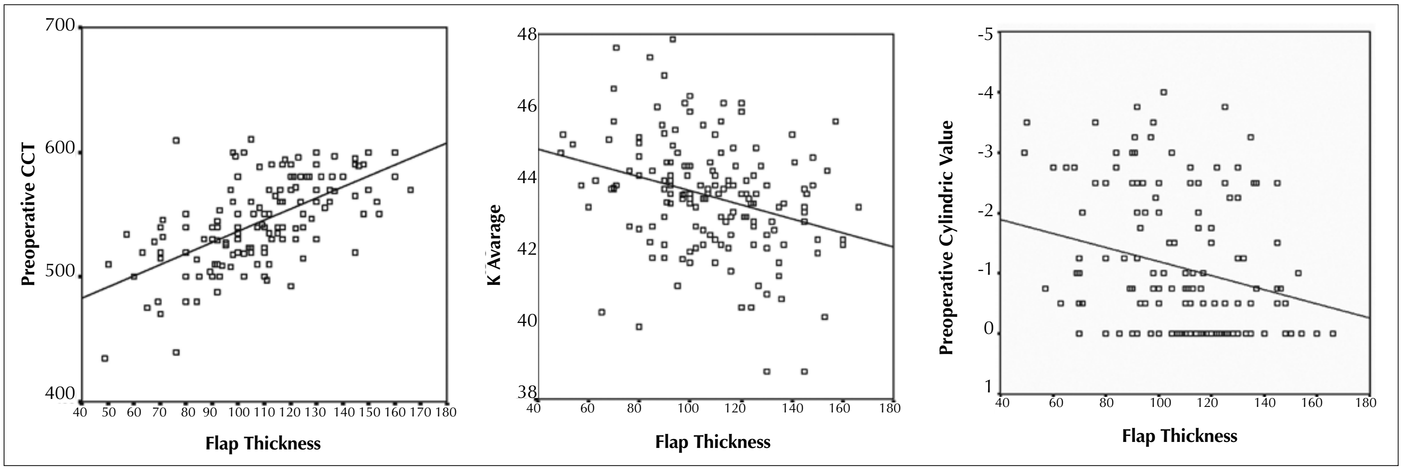

Figure 1. Correlations between central corneal thickness (CCT) and flap thickness (*A-left-up*), between keratometric values and flap thickness (*B-right-up*), and between preoperative cylindrical refraction values and flap thickness (*C-right-down*)

Table 2. Intended versus obtained flap thickness values with two different microkeratome types

Intended flap thickness (µm)	Obtained flap thickness (µm)	t	p
130	87.8±15.8 (49–117)	21.349	<0.001
160	120.8±20.2 (60–166)	18.782	<0.001

All data are presented as mean±SD (min–max)

Table 3. The difference in flap thickness values between the right and left eyes for both groups

Intended flap thickness (µm)	Eye	Flap thickness (µm)	t*	p
130	Right Left	88.5±14.2 87.5±17.2	0.514	0.609
160	Right Left	129.8±15.8 111.0±19.5	5.517	<0.001

Data are presented as mean±SD

*Comparison between the right and left eyes

1 and 45 patients in group 2 were operated bilaterally. In group 1, mean FT values were 88.5±14.2 µm in the right eye and 87.5±17.2 µm in the left eye. Although the mean FT values of the left eye were thinner than those of the right eye in group 1, the difference was not statistically significant (t=0.514, p=0.609). However, in group 2, the mean FT values were 129.8±15.8 µm in the right eye and 111±19.5 µm in the left eye, and the difference between these values was statistically significant (t=5.517, p<0.001) (Table 3). Although the obtained flaps were thinner than intended, especially after the second usage of the microkeratome, no flap-related complications, such as buttonholes or free flaps, were encountered.

Discussion

The efficacy and predictability of FT in LASIK are still important factors in achieving an optimal and satisfactory refractive outcome. An ideal microkeratome should produce flaps of a predetermined thickness in all patients, without being influenced by individual ocular factors. Theoretically, the distance between the fixed microkeratome plate and the edge of the metal blade determines the thickness of the flap during the flap cut (11). Several other variables are important in determining FT, including the quality and entry angle of the blade, the translation and oscillation rate, the consistency across the cornea, suction ring pressure setting and suction duration, the mechanism of the cut, room humidity, preoperative CCT, and corneal diameter (11, 15-20).

One of the most important problems of different microkeratomes is the tendency of the actual FT to be thinner than the predicted value. In this study, similar to the findings of previous studies, thinner flaps than intended were achieved in all groups (14, 21, 22). Still, while there was substantial variation in FT, no buttonholes or other significant flap-related complications were observed during LASIK surgery. When the microkeratome types were questioned, attention must be paid to prevent flap complications especially if a microkeratome head of 130 µm or less is used. There was a large difference between the achieved and intended FT in our study (42.2 µm in group 1 and 39.2 µm in group 2).

While thinner flaps (<90 µm) can increase the risk of haze and striae, thicker flaps (>150 µm) can reduce the range of refractive correction and may negatively affect the biomechanical stability of the cornea (23-25). Generally, the suggested optimum FT is around 110 µm, to provide the best biomechanical stability and corneal transparency (23). Solomon and colleagues found thinner but near-optimum flaps by using the MK-2000 and a 130 µm microkeratome head (mean FT±SD, 111±19 µm) (26). As shown in this study, previous studies have also reported thinner flaps (Naripthaphan 2001, 122±18 µm; Arbelaez 2002, 116±19 µm; Shemesh 2002, 127±4 µm) by using MK-2000 and 130 µm microkeratome heads (15, 18, 27). Schumer and Bains (28) reported different results using two different models of 130 µm microkeratome head (models 121 and 65). Their results were 129±22 µm with model 121 and 152±25 µm with model 65. They achieved thicker flaps with the second model, which differs from the results of other studies.

The worst postoperative LASIK complication is corneal ectasia, which is believed to originate from the weakening of the biomechanical structure of the cornea (10-12). Therefore, the predictability of FT before an operation and the thickness of residual stromal bed after the ablation are very important for preventing ectasia development.

Another common feature of microkeratomes appears to be the difference in results between the first and second usage of the blade (15, 19, 27, 29, 30). In the present study, the right eyes were operated before the left eyes and first flaps were found to be thicker than the second flaps in all bilateral cases. Previous reports have shown that a thinner flap results from making the second cut using the same blade, and the main reason for this might be due to the fact that the blade becomes duller after the first use (16, 20, 30). The first cut probably affects the sharpness of the blade and even minor changes in sharpness might cause variations between the first and second cuts (4).

In this study, no correlation was found between age and FT, as reported in the study by Hsu and colleagues (31). However, two studies (7, 9) reported that increasing age was found to be associated with thinner flaps for automated corneal shaper (ACS), Summit Krumeich Barraquer (SKBM) and Moria M2™, respectively.

Several reports have confirmed a positive correlation between CCT and FT as found in our study (7, 19, 26, 30, 32-34). The reason for this correlation may be the fact that a thicker cornea is more compressible in the superficial corneal area than a thinner cornea (20). It is clear that some microkeratomes are prone to CCT variations, which can be attributed to the microkeratome's design characteristics (the blade, head, and electromechanical parts) (6). In our study, the CCT, the patient's refraction, and the amount of ablation planned were considered when deciding whether to use the 130 μm or 160 μm microkeratome head. For instance, if the patient had a thin cornea and high myopia, the 130 μm microkeratome head was preferred. This preference might be the reason we achieved thin flaps in thin corneas and thick flaps in thick corneas.

In the present study, a negative correlation was found between keratometric power and FT, similar to Flanagan and Binder's study (9) that used the ACS microkeratome. On the other hand, a significant positive correlation was found between keratometric power and FT using the Rondo microkeratome in another study (6). In other studies with the MK-2000 microkeratome, no correlation between keratometric power and FT was found (28, 30). Previous studies also reported no correlation between keratometric power and FT by using microkeratomes other than MK-2000 (26, 35-37). The result of a negative correlation between keratometric power and FT in our study shows that a thin flap may be obtained if the patient has a steep cornea. Leung and colleagues reported six cases of buttonholed flaps with a mean keratometric value of 44.20 D (38). Gimbel and colleagues showed that the risk of buttonholes and thin-flap complications were especially increased in corneas steeper than 46 D. Therefore, the use of thicker microkeratomes and the creation of deeper incisions may be advisable. The risk of a free flap increases in a cornea flatter than 42 D. Most of the factors that lead to a thin flap may also lead to a free flap (14).

Actual FT values with different microkeratome heads and also first and second usage of the same blade revealed significant variation after LASIK surgery. Therefore, it is recommended that stromal bed thickness should be routinely measured before and after flap creation to ensure that enough tissue would remain after surgery. Although the MK-2000 microkeratome creates flaps that are thinner than expected, it may be used safely without the development of corneal ectasia.

Conclusion

Actual FT values with different microkeratome heads and also first and second usage of the same blade revealed significant variation after LASIK surgery. Therefore, it is recommended that stromal bed thickness should be routinely measured before and after flap creation to ensure that enough tissue would remain after surgery. Although the MK-2000 microkeratome creates flaps that are thinner than expected, it may be used safely without the development of corneal ectasia.

Conflict of Interest
No conflict of interest was declared by the authors.

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Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Erciyes University.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Authors' contributions: Conceived and designed the experiments or case: HA. Performed the experiments or case: EK. Analysed the data: HA and EK. Wrote the paper: HA. All authors have read and approved the final manuscript.

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